

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)




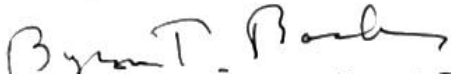
May 13, 2022

Memorandum:

Subject: Acute Toxicity Review for EPA File Symbol: 33427-RU

Applicant: Aceto US, L.L.C.
Product Name: Aceto Bentazon Technical
DP Barcode: D464815
Decision No.: 569317
Action Code: R334
PC Code(s): 275200 Bentazon (99.07%)

From: Odbert Triplett, Biologist 
Chemistry, Inerts and Toxicology Assessment Branch (CITAB)
Registration Division (7505T)

Through: Byron T. Backus, Ph.D., Biologist 
Chemistry, Inerts and Toxicology Assessment Branch (CITAB)
Registration Division (7505T)

To: Endia Blunt
Mindy Ondish, RM 23
Herbicide Branch Registration Division (7505T)

Formulation from label:

<u>Active Ingredient(s):</u>	<u>% by wt.</u>
Bentazon, 3-(1-methylethyl)-1 <i>H</i> -2,1,3-benzothiadiazin-4(3 <i>H</i>)-one 2,2-dioxide	99.07%
<u>Other Ingredients:</u>	0.93%
Total:	100.00%

BACKGROUND: This is a resubmission with updated data citations as an issue was noted with two of the previously cited studies MRID 00072790 and 00072791 (Triplett, O., DP461016), which were conducted on a formulation containing approximately 21.8% of the sodium salt of bentazon and 20% atrazine and could not be used to satisfy the dermal and eye irritation study requirements as the MRID citations to 00072790 and 00072791 on page 17 of the November 15, 1999 HED Risk Assessment are erroneous.

MRIDs 00135394, 00135399, 00164088 (TXR# 0013842) and 49043417 (TXR 50134344) were found to be acceptable to use for this registration in the previous review. The registrant has cited two new studies MRID 49043418 (Acute Inhalation) and 49043419 (Primary Eye Irritation) to satisfy these remaining acute toxicity requirements.

The newly cited studies were reviewed and classified as acceptable in a previous review (TXR 50134344) along with MRID49043417 and satisfied the acute inhalation, eye irritation and dermal irritation study requirements for the registration of 70506-300 (now 91813-44, with a label declaration of 98.6% bentazon).

All the studies cited for this resubmission can be used to satisfy the acute toxicity requirements for this registration.

RECOMMENDATIONS:

1. After comparing the proposed CSF, dated December 28, 2021, for Aceto Bentazon Technical, EPA File Symbol: 33427-RU with the basic CSF for A319.06, EPA File Symbol EPA Reg. No. 91813-44 (previously 70506-GNN), dated December 20, 2012, it is concluded the two formulations are toxicologically similar and have the same acute toxicity profile.
2. The MRIDs 00135394, 00135399, 49043417-19, and 00164088 can be used to satisfy the acute toxicity requirements for the registration of 33427-RU.
3. The proposed Basic CSF must be reviewed and accepted by the product chemists in the Chemistry, Inerts and Toxicology Assessment Branch.
4. The following constitutes the toxicology profile assigned to Aceto Bentazon Technical, EPA File Symbol: 33427-RU:

Acute oral toxicity	cited	III	MRID	00135394*
Acute dermal toxicity	cited	III	MRID	00135399*
Acute inhalation toxicity	cited	III	MRID	49043417@
Primary eye irritation	cited	II	MRID	49043418@
Primary dermal irritation	cited	IV	MRID	49043419@
Dermal sensitization	cited	Positive	MRID	00164088*

* TXR# 0013842, @ TXR 50134344

Based on the acute toxicity profile given above, with additional information from the CSF and proposed uses, the following are the updated precautionary and first aid statements as obtained from the Label Review System:

Product ID: 33427-RU

Product Name: Aceto Bentazon Technical

Precautionary Statements:

Keep out of Reach of Children.

Signal Word: **WARNING**

Poison Label: **None**

Hazards to Humans and Domestic Animals:

Causes substantial but temporary eye injury. Harmful if swallowed. Harmful if absorbed through skin. Harmful if inhaled.

Do not get in eyes or on clothing. Wear (specify appropriate protective eyewear such as goggles, face shield, or safety glasses). Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.; Avoid contact with skin. **Avoid breathing (dust, vapor or spray mist).** Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Wear long-sleeved shirt and long pants, socks, shoes, and (waterproof or chemical-resistant) gloves.

*The registrant needs to include the precautionary statement **bolded** above.*

First Aid:

If in eyes:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.
- Call a poison control center or doctor for treatment advice.

If swallowed:

- Call a poison control center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to do so by a poison control center or doctor.
- Do not give anything by mouth to an unconscious person.

If on skin or clothing:

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment advice.

If inhaled:

- Move person to fresh air.
- If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.
- Call a poison control center or doctor for treatment advice.

EPA encourages but does not require (see PR Notice 2001-1) registrants to include a company telephone number or toll-free hotline for emergency information in the first aid section. If a number is included, confusion can be avoided by specifying emergency vs non-emergency numbers. It should include a phrase or statement indicating the kinds of information the number should be used for and it may include hours of service. The following are examples of appropriate statements that may be included on the label:

- Have the product container or label with you when calling a poison control center or doctor or going for treatment.
- For medical emergencies, call the poison control center at 1-800-222-1222.
- For general information about this product, call 1-XXX-XXX-XXXX [may include hours of service], or contact the National Pesticides Information Center (NPIC) at 1-800-858-7378, Monday through Friday, 8 AM to 12 PM PST, or at <http://npic.orst.edu>.

The proposed label includes a telephone number and a statement to have the product container and label when calling to a poison control center or doctor, along with a contact phone number for emergency medical information. These statements are appropriate and acceptable.